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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,572	04/28/2006	Ushio Iwamoto	P28765	8899
7055 7590 11/14/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER UNDERDAHL, THANE E	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 11/14/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/559,572

Applicant(s)

IWAMOTO ET AL.

Examiner

Thane Underdahl

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 105-120 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105-120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/23/06 and 4/7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's response, with traverse, to the Restriction/Election requirement filed on 8/13/07 is acknowledged. The applicant elected Group II which includes claims 105-120.

The Applicant argues that the restriction requirement does not make the required showing of lack of unity regardless of the "offhand" reference to the patent cited. The Examiner notes that there are no requirements in the citation of 37 C.F.R. 1.475 as to the detail required to show lack of unity. However in the interest of compact prosecution a cursory review of U.S. Patent # 5510102 teaches an wound healing composition that is made of plasma, platelets and a porous polymer such as alginate that can form a gel that covers the wound like a sheet (see summary of invention and col 8, lines 64-67). Therefore this teaches the composition of claim 91 and as such unity is not present.

Therefore, the Restriction/Election requirement is therefore made FINAL and the elected species and the claims they include will now be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 105-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claim 105 and several of the following claims include the phrase "sheet-like porous body" as a wound-healing material. It is unclear to the Examiner if the pores of the body are "sheet-like" or if the wound-healing material is sheet-like. Furthermore, the term body used in this context is unclear since this imparts that there are several auxiliary components (or appendages) to the material, but this contradicts with the phrase "sheet-like" which implies a single, continuous, piece. Claim 107 is indefinite since it used the phrase "sponge construct" this term is not clear if the material is indeed a sponge or simply a porous media.

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Clarification is required. Claim 108 contains the phrase "capable of selective separation of blood cells". The term capable is indefinite since it makes the limitation optional since the method does not include a step of actually selectively separating the blood cells.

Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure (M.P.E.P. § 2111.04). Furthermore it is not clear what is being separated from the blood cells.

Claim 109 and 111 are indefinite since the relationship to how the leukocytes and platelets are trapped in the material via a general filtration step or extracorporeal circulation is unclear. Claim 110 includes the phrase "a once-through system". It is unclear to the Examiner if this means method is carried out in a disposable system or is only passed through the filtration system once. Clarification is required. Claim 113 contains the limitation "mature cells". It is unclear if this means the cells are obtained from a mature individual or the cells themselves have matured according to their lifecycle. Furthermore, the maturity of the individual is indefinite since different species mature in different times. Clarification is required.

Claims 112-114 and 117 are indefinite since they depend from claim 105 but include the limitation of "cell suspension". There is improper antecedent basis for cell suspension, since claim 105 makes no mention of such a limitation. It is unclear to the Examiner what cell suspension is being used in the steps limited in claims 112-114 and 117. Clarification is required. Claim 115 is indefinite since it contains a step of "culturing" the material that has trapped leukocytes and/or platelets. It is unclear to the

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Examiner what cells or micro-organisms are being cultured in this step. Clarification is required. Furthermore the steps limited in claim 117 are indefinite because step of "followed by concentration". It is unclear if this step is to be included with both alternatives of the step or the step of filtration by cell suspension.

Furthermore claim 105 and many of its dependants contain the phrase "and/or". The phrase "and/or" it is unclear to the examiner if the limitations linked by the phrase are a combination or an alternative.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 105, 106, 107, 115 and 120 are rejected under 35 U.S.C. 102(b) as being anticipated by Slepain et al. (U.S. Patent # 5843156).

These claims are drawn to a method to prepare a wound-healing material. That comprises a step of trapping at least leukocytes or platelets in a porous sheet with a thickness of 0.01 mm to 3 mm. The material can be a porous material with pore diameter of 1.0 to 40 μ m. The claims further limit the method to culturing such a sheet and obtaining a sheet made by such a process.

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Slepain et al. teach a polymeric material that contains entrapped platelets. This material creates a coating sheet over a wound to form a porous layer (col 11, lines 28-40). The sheet is 0.001 to 1.0 mm in thickness (col 11, line 33). Slepain et al. further teaches a porous material that can entrap platelets and other cells (col 8, lines 45-50) and the pores are 30 to 40 μm in diameter (col 11, lines 30-35).

Therefore the reference anticipates claims 105, 106, 107, 115 and 120.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 105-115 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepain et al. (U.S. Patent # 5843156) as applied to claims 105, 106, 107, 115 and 120 above and for the following rational.

The description and rejection of claims 105, 106, 115 and 120 are listed in the 35 U.S.C § 102(b) rejection above. Because of the indefiniteness of claims 107-113 detailed above the Examiner will interpret the claims as follows to expedite prosecution. Claim 107 is to a material that is a sheet made of either a nonwoven fabric with a fiber diameter to 0.3 to 50 μm and a density of 0.05 to 0.5 g/cm^3 or a porous material with a pore diameter of 1.0 to 40 μm . Claim 108 limits that the porous material traps

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leukocytes and/or platelets more selectively than erythrocytes. Claims 109-111 limit that the platelets or leukocytes are entrapped in the material. Claims 112-114 limit the origin of the platelets or leukocytes.

Slepain et al. does teach a porous material that can entrap platelets and other cells (col 8, lines 45-50) and the pores are 30 to 40 μm in diameter (col 11, lines 30-35). What Slepain et al. does not teach is that the sheet preferentially entraps platelets and leukocytes to erythrocytes. However Slepain et al. does teach that pore size can be adjusted to exclude large cells (col 11, lines 30-35) such as erythrocytes to "satisfy a wide variety of biological or clinical situations" (col 11, lines 39 and 40). Therefore it would have been obvious to someone skilled in the art to modify the material to have pores large enough to exclude large cells but incorporate platelets.

Furthermore while claims 109 to 114 limit the origin of the platelets such as the time acquired and the source. However, it would have been obvious to someone skilled in the art to obtain the platelets from these or other sources since it is well known in the art that platelets can be collected at various times and from various sources such as autologous blood or allogeneic blood since these would serve the same purpose in the method (M.P.E.P. § 2144.06).

Therefore the references listed above renders obvious claims 105-115 and 120.

Claims 105-115, and 117-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepain et al. as applied to claims 105-115 and 120 above, and further in view of Hood (U.S. Patent # 5733545).

The description and rejection of claims 105-115 and 120 are listed in the 35 U.S.C § 103(a) rejection above. Claims 117-119 adds the step of incorporating fibrins into the wound healing material and washing the material. This process is carried out in a openable liquid-tight container.

While Slepain et al. do teach that fibrin can be included in their material (Slepain col 14, lines 44-48). However Slepain et al. do not teach that the method step includes filtration followed by concentration. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Hood. Like Slepain et al., Hood teach a wound sealant composition made from platelets and at least leukocytes (Hood, see Abstract). Hood also teach a wound sealant composition that contains fibrin that is made by filtering the composition into a flexible sheet (Hood, col 6, lines 20-25). Therefore it would have been obvious to combine the teachings of Slepain et al. and Hood since both teach a similar methods for the purpose of wound healing. Since both methods are known in the art it would be obvious to combine already known methods that achieve the same result it would be obvious to combine those methods to achieve the same predicted result, which in this case is the creating of a wound sealant composition (KSR International Co. v. Teleflex Inc.).

Furthermore while claims 118 and 119 add the steps of washing the wound healing material which is not explicitly taught in either of the above references this would be obvious to one of ordinary skill in the art. Since washing and sterilizing any material before it is applied to an open wound is soundly obvious in the art. In, common wound sealing methods, such as the application of bandages, one of ordinary skill in the

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art would rightly assume that the commercially available bandages were washed and sterilized in the factory before they were applied. The limitation in claim 119 that the washing be done in a water tight container with an inlet and outlet is also obvious to one of ordinary skill in the art since washing commonly involves water and agitation. One of ordinary skill in the art would recognize that agitating water in a container that is not liquid tight is would lead to an unnecessary mess. Furthermore it would have been obvious to someone skilled in the art to use a container with a liquid inlet and outlet so as to easily introduce and expel the water during the washing process, similar to the method used by a typical household washing machine.

Therefore the references listed above renders obvious claims 105-115, and 117-120.

Claims 105-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian et al. and Hood as applied to claims 105-115, and 117-120 above, and further in view of van Blitterswijk et al. (U.S. Patent # 6383220).

The description and rejection of claims 105-115 and 117-120 are listed in the 35 U.S.C § 103(a) rejection above. Claim 116 incorporates fibroblasts into a wound healing material.

While Slepian and Hood et al. teach a material that is for wound healing and contains platelets as well as fibroblast growth factors (Slepian, col 8, lines 5-10). They do not teach the incorporation of fibroblasts into the sheet-like body. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in

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view of the teachings of van Blitterswijk et al. He teach the a wound-healing composition that incorporates fibroblasts (van Blitterswijk, col 4 lines 1-5 and 37-40). It would have been obvious to someone skilled in the art to add fibroblasts to wound healing method taught by Slepian and Hood. Slepian et al. provides motivation by include a fibroblast growth factor to promote the accumulation and incorporation of fibroblasts into the wound to expedite healing. The reasonable expectation of success is provided by van Blitterswijk et al. who teach that indeed, fibroblasts can be incorporated into the material to expedite wound healing. Therefore the references listed above renders obvious claims 105-120.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571)

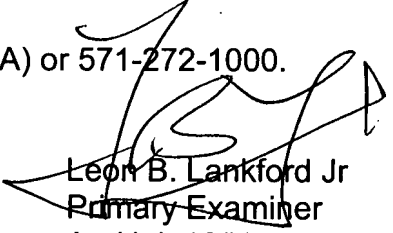
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272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651



Leon B. Lankford Jr
Primary Examiner
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IFW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Ushio IWAMOTO et al.

Examiner: unknown

Appln. No. : 10/559,572
(National Stage of PCT/JP2004/008254)

Art Unit: unknown

I.A. Filed : June 7, 2004

For : WOUND-HEALING PROMOTING MATERIAL

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AMENDMENT
Randolph Building
401 Dulany Street
Alexandria VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. 1.56, 1.97, and 1.98,
Applicant hereby brings the following information to the attention of the Examiner.

An English translation of the International Preliminary Report issued in
connection with counterpart International Application No. PCT/JP2004/008254²⁷ is
enclosed. Copies of the documents cited therein are not enclosed herein because they
were submitted with the Information Disclosure Statement dated April 7, 2006. The
Examiner is invited to review the enclosed International Preliminary Report to inspect
the relevance indicated during international examination with respect to the documents
cited therein.

Because a first Office Action has not been received, it is believed that no fee
should be necessary for consideration of this Information Disclosure Statement.
However, if a fee is required for any reason, then this should be considered express

P28765.A03.DOC

authorization to charge any necessary fee for consideration of this Information Disclosure Statement to Deposit Account No. 19-0089.


Should there be any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.


/TU/

/Thane Underdahl/

11/05/2007

Respectfully submitted,
Ushio IWAMOTO et al.


Bruce H. Bernstein
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42,357

May 23, 2006
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